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12/23/2009

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-10 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 2 recites the limitation "tissue engaging elements". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-5, 7-9, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (5,192,302) in view of Martinez et al. (5,593,412).

Kensey discloses the following claimed limitations:

Claim 2: A method for delivering a closure element (20) to seal an opening through tissue, the closure element being carried on a carrier assembly (30) slidably disposed on a proximal end (58) of an elongate member (52) such that a proximal end of the closure element is spaced apart from an outer surface of the elongate member (Fig. 2), the method comprising: inserting a distal end (56) of the elongate member into an

Art Unit: 3773

opening through tissue (Fig. 4), the elongate member having a distal end (56) and a proximal end (58) and a skin (26) overlying at least a portion of the outer surface of the elongate member between the distal end and proximal end and at least partially overlying the carrier assembly (Fig. 4); advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member (Fig. 2-7), thereby advancing the closure element towards the distal end of the elongate member (Fig. 4); engaging tissue adjacent the distal end of the elongate member with tissue engaging elements on the closure element (Fig. 8); and withdrawing the elongate member from the opening, thereby leaving the closure element to close the opening (Fig. 8, Col. 7 Lines 67-68, and Col. 8 Lines 49-55).

Claim 8: Wherein the opening through tissue extends through one or more layers of fascia, and wherein the skin facilitates advancing the closure element through the one or more layers of fascia (Fig. 4).

Claim 9: Wherein the opening through tissue communicates with a blood vessel, and wherein leaving the closure element to close the opening comprises leaving the closure element to substantially seal the opening from blood flow therethrough with the closure element (Fig. 8).

Claim 14: Inserting a distal end of an actuator member (38) between the proximal end of the closure element and the outer surface of the elongate member until the distal end of the actuator member is coupled with the closure element and advancing the actuator member in a distal direction to advance the carrier assembly along the elongate member (Fig. 3).

Claim 15: Manipulating the actuator member to deploy the closure element and engage the tissue adjacent the distal end of the elongate member (Fig. 4-8).

Kensey discloses the claimed invention except that the closure element causes the skin to separate.

Martinez teaches a skin (18) that separates when the implant (24) is deployed (Fig. 3-5). Furthermore, Martinez discloses that the skin comprises a weakened region (41-45) extending towards the distal end of the elongated member (Fig. 1-2); that the skin (18) comprising a flap (fingers 51-55) extending generally axially along the outer surface of the elongate member (12) and overlying an adjacent region of the skin (Fig. 1-3 where the flaps are adjacent to the weakened areas (41-45) which attaches all the fingers together as best seen in Fig. 2A) fingers as seen in the figures), and wherein the flap is released from the adjacent region (Fig. 2B-5) as the carrier assembly (14) is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface (Fig. 2-5); that the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue and that it allows for retraction of the sheath and allows for expansion for the element onto which it is disposed (Col. 3, Lines 30-42 and Col. 4, Lines 53-67 and Col. 5 Lines 1-2); and that the cross-section of the skin when expanded is larger than the cross-section of the elongated member (14) (Fig. 5).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Kensey with a splittable skin, as taught by Martinez, since it was known in the art that skins or sleeves are commonly used in deployment devices to conveniently protect delivery devices and are often subsequently opened or removed in order to unveil the delivery device without additional manipulation by a secondary instrument. Furthermore, it is well known in the art the use of peel-away sheaths or splittable sheaths in order to prevent the reuse of the device as well as making the outer diameter of the device of a smaller diameter when delivered to avoid any complications.

Response to Arguments

6. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3773

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773

Application/Control Number: 10/682,459
Art Unit: 3773

Page 7